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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,231	03/25/2004	Mary Jo. A. Toomey	22486/19 (7058)	9460
7590 11/20/2006		EXAMINER		
Brown Rudnick Berlack Israels LLP			CHAPMAN, GINGER T	
One Financial Center Boston, MA 02111			ART UNIT	PAPER NUMBER
•		•	3761	
			DATE MAILED: 11/20/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Author Occasions	10/810,231	TOOMEY ET AL.				
Office Action Summary	Examiner	Art Unit				
	Ginger T. Chapman	3761				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on 28 Au	iaust 2006.					
	action is non-final.					
,	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
•	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-12 and 25-41</u> is/are pending in the application.						
4a) Of the above claim(s) 25-41 is/are withdraw	4a) Of the above claim(s) <u>25-41</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-12</u> is/are rejected.	•					
7) Claim(s) is/are objected to						
•						
Application Papers						
9) The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>23 September 2004</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date Solution Paper No(s)/Mail Date Other:						

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species 1 in the reply filed on 28 August 2006 is acknowledged.

New claims 25-41 are added by way of applicant's amendment. Claims 1-12 and 25-41 are pending in the application.

Newly submitted claims 25-41 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 25-41 are directed to a holder member having an internal penetrating member defining an internal conduit in fluid communication with the fluid outlet of the housing member. These limitations are not required for Species 1 and additional searches would of necessity be required for the combinations of species. Where claims to another invention are added and entered in the application before an action is given, they are treated as original claims for purposes of restriction only. The claims originally presented and acted upon by the Office on their merits determine the invention elected by an applicant in the application, and in any request for continued examination which has been filed for the application. Subsequently presented claims to an invention other that that acted upon are treated as provided in MPEP § 821.03. See MPEP § 818.02(a).

Claims held to be drawn to nonelected inventions, including claims to nonelected species are treated as indicated in MPEP § 821.01 through § 821.03. All claims that the examiner holds as not being directed to the elected subject matter are withdrawn from further consideration by the examiner in accordance with 37 CFR 1.142 (b). Applicant may traverse the requirement pursuant to 37 CFR 1.143.

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This invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, newly added claims 25-41 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of the claims

By way of Applicants' amendment filed 28 August 2006, claims 13-24 are cancelled, claims 25-41 are added. Claims 1-12 and 25-41 are pending in the application. Claims 25-41 are withdrawn from consideration as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Grossman (US 5,342,328).

With regard to claim 1, as best depicted in Figures 7 and 8, Grossman et al disclose a fluid collection apparatus (fig. 3) comprising: a housing (11) configured for receipt of fluid and having a first surface which defines a needleless first mating portion (15); a holder (16) having a first end and a second end (fig. 4) configured to receive an evacuated tube (30), the first end (17b) defining a second mating portion (40) on an outer surface thereof (43) which is in fluid communication (45) with the evacuated tube (30), the first mating portion (17b) sealingly engages the second mating portion (40) (c. 4, Il. 25-30) to establish fluid communication therebetween, disclosed in the instant specification at p. 13, Il. 1-15 as a suitable embodiment of the instant claimed invention; and a base (13) disposed within the housing and being configured for support thereof (c. 3, Il. 8-9).

With regard to claim 2, as best depicted in Figure 2, Grossman et al disclose the base (13) has a top opening adapted for receiving the housing (15, 11).

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With regard to claim 3, as best depicted in Figure 2, Grossman et al disclose the base (13) is adapted for standing on a surface (c. 3, ll. 8-9).

With regard to claim 4, as best depicted in Figures 2 and 4, Grossman et al disclose the base (13) is configured to enclose holder (16).

With regard to claim 5, Grossman et al disclose the housing (11) has a flange portion (43) extending radially therefrom that engages the base (15).

With regard to claims 6 and 7, Grossman et al disclose at least one rib (19) and a plurality of ribs (19).

With regard to claim 8, as best depicted in Figures 2 and 4, Grossman et al disclose the base (13) is configured to hold housing (11), holder (16) and an evacuated tube (30) in holder (16).

With regard to claims 10 and 11, Grossman et al disclose a removable cap (22) adapted to removably enclose an opening of the housing (11) and provides a fluid seal within housing.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman (US 5,342,328).

With regard to claim 9, Grossman et al disclose the base (13) includes a plurality of sidewall extensions (13) but does not disclose the sidewall extensions separated by cutout portions. Grossman at c. 3, ll. 8-9 teaches that the sidewall extensions provide a level support base for standing housing on a level surface thus disclosing a desire for means to support and stand the apparatus on a level surface. As seen in Figures 2 and 4, Grossman teaches the sidewall extensions providing a level support base for standing the apparatus comprising its

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housing on a level surface. After review of the instant specification, in particular at p. 16, ll. 13-21 and the instant Figure 12, disclosing that the cutouts are optional depending on the material used, it is noted that Applicant provides no criticality for the cutout portions. The specification contains no disclosure of either the critical nature of the claim limitations nor any unexpected results arising therefrom, and that as such the limitations were arbitrary and therefore obvious. It appears the invention would work equally well with or without the cutout portions as best depicted in the instant figure 12. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the sidewall extensions with cutout portions, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. *In re Karlson*, 136 USPO 184.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman (US 5,342,328) in view of Szeles (EP 1,295,561 A1).

With regard to claim 12, Grossman et al disclose the invention substantially as claimed except for the removable cap includes a finger grip. Szeles, at c. 7 [0039] to c. 8, ll. 1-5 teaches the ability of a removable cap (12, 40) to include mating threads and ridges and protrusions to provide means for the user of the apparatus to attach the cap to the container as described at c. 9, [0043]. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the cap of Grossman including gripping portions as taught by Szeles since Szeles states at c. 3 to c. 4, [0021] that the advantage of forming a cap with this

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design is that the cap seals the container and at [0043] that the cap can be removed and reapplied by the user of the apparatus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571) 272-4934. The examiner can normally be reached on Monday through Friday 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ginger Chapman

Examiner, Art Unit 3761

11/13/06

TATYANA ZALUKAEVA SUPERVISORY PRIMARY EXAMINER